

Inventor(s): John C. Reed
Serial No.: 09/350,518
Filed: July 9, 1999
Page 2

CURRENT STATUS OF ALL CLAIMS

Claims 1-10 cancelled.

11. (Previously amended) The method of claim 16, wherein said level of BAG-1 protein expression is determined by measuring the amount of BAG-1 protein product using an immunoassay.

12. (Original) The method of claim 11, wherein said immunoassay is an immuno-polymerase chain reaction (immuno-PCR) assay.

13. (Previously amended) The method of claim 16, wherein said level of BAG-1 protein expression is determined prior to lymph node involvement of said cancer.

14. (Previously amended) The method of claim 16, wherein said level of BAG-1 protein expression is determined after lymph node involvement of said cancer.

Claim 15 cancelled.

16. (Currently amended) A method for prognosis of disease-free or overall survival of an individual having a breast cancer tumor, comprising determining, using a BAG-1 specific antibody, the level of BAG-1 protein expression in a sample of said tumor or tumor cells from a body fluid during stage I or stage II of said cancer, wherein a high level of BAG-1 expression relative to a reference level of BAG-1 expression correlates positively with disease-free or overall survival.

Claims 17-19 cancelled.

20. (Currently amended) The method of claim 16, wherein said level of BAG-1 protein expression is determined by measuring the level of BAG-1 protein that is detectable in samples selected from ~~the group consisting of~~ breast tumor tissue and breast tumor cells from a body fluid, ~~blood, serum, and plasma~~.

Inventor(s): John C. Reed
Serial No.: 09/350,518
Filed: July 9, 1999
Page 3

21. (Previously amended) The method of claim 16, further comprising determining if said level of BAG-1 protein expression represents an overproduction that is above a reference level of BAG-1 expression.

22. (Previously amended) The method of claim 21, wherein said reference level of BAG-1 expression is determined by a histogram analysis.

23. (Previously amended) The method of claim 21, wherein said reference level of BAG-1 expression is determined relative to a level of BAG-1 expression produced by *in vitro* cultured cells which produce BAG-1.

24. (Previously amended) The method of claim 21, wherein said reference level of BAG-1 expression is determined relative to a level of BAG-1 expression in non-cancerous cells.

25. (Currently amended) A method for predicting the risk of tumor recurrence or spread in an individual having a breast cancer tumor, comprising determining, using a BAG-1 specific antibody, the level of BAG-1 protein expression in a sample of said tumor or **breast tumor cells from a** body fluid from said individual during stage I or stage II of said cancer, wherein a high level of BAG-1 expression **relative to a reference level of BAG-1 expression** correlates negatively with tumor recurrence or spread.

26. (Previously amended) The method of claim 25, further comprising:

(a) determining an overproduction level for BAG-1 protein, said level being in excess of a minimum amount statistically determined to be indicative of decreased likelihood of tumor recurrence or spread;

(b) determining the level of BAG-1 protein expression in said tumor sample;
and

Inventor(s): John C. Reed
Serial No.: 09/350,518
Filed: July 9, 1999
Page 4

(c) predicting said risk of tumor recurrence or spread wherein an overproduction level of BAG-1 protein in the tumor sample is negatively associated with the likelihood of tumor recurrence or spread.

27. (Currently amended) A method for screening a breast cancer patient to determine the risk of tumor metastasis or chance of survival, said method comprising:

(a) determining, using a BAG-1 specific antibody, the level of expression of BAG-1 protein in a cancerous tissue sample or **tumor cells from** a body fluid sample from said patient during stage I or stage II of said cancer; and

(b) classifying a patient having high levels of expression of BAG-1 protein, relative to a reference level, as being less likely to suffer tumor metastasis or having an increased chance of survival.

Claims 28-31 cancelled.

32. (Previously amended) The method of claim 27, wherein the level of expression of BAG-1 protein is measured using an immunoassay.

33. The method of claim 32, wherein said immunoassay is an immuno-polymerase chain reaction assay.

34. (Currently amended) A method for determining the proper course of treatment for a patient suffering from breast cancer, said method comprising:

(a) determining, using a BAG-1 specific antibody, the level of BAG-1 protein expression in a cancerous tissue sample or **tumor cells from a** body fluid from said patient during stage I or stage II of said cancer;

(b) identifying a first group of patients having low levels of BAG-1 expression relative to a reference level of BAG-1 expression, which first group of patients may require treatment proper for patients having a lesser chance of survival or being more likely to suffer tumor recurrence or spread; and

(c) identifying a second group of patients having high levels of BAG-1 expression relative to a reference level of BAG-1 expression, which second group of patients may require treatment proper for patients having a greater chance of survival and being less likely to suffer tumor recurrence or spread.

Claim 35 cancelled.

36. (Previously amended) The method of claim 34, wherein said level of BAG-1 protein expression is determined prior to lymph node involvement.

37. (Previously amended) The method of claim 34, wherein said level of BAG-1 protein expression is determined after lymph node involvement of said cancer.

Claims 38-43 cancelled.

44. (Currently amended) A method for determining risk of tumor recurrence or spread in a patient suffering from breast cancer, said method comprising:

(a) determining, using a BAG-1 specific antibody, the level of expression of BAG-1 protein in a cancerous tissue of a patient during stage I or stage II of said cancer; and

(b) classifying said patient as belonging either to a first group of patients having high levels of expression of BAG-1 relative to a reference level of BAG-1 expression, or a second group of patients having low levels of expression of BAG-1 relative to a reference level of BAG-1 expression.

Inventor(s): John C. Reed
Serial No.: 09/350,518
Filed: July 9, 1999
Page 6

wherein said first group has a lower likelihood of tumor recurrence or spread than said second group, thereby determining a lower risk of tumor recurrence or spread in the first group of patients suffering from breast cancer.

Claims 45 – 49 cancelled.

50. (Previously amended) The method of claim 16, wherein said level of BAG-1 protein expression is determined by measuring the level of BAG-1 protein in a sample of breast tumor tissue.

51. (Previously amended) The method of claim 25, wherein said level of BAG-1 protein expression is determined by measuring the level of BAG-1 protein in a sample of breast tumor tissue.

52. (Previously amended) The method of claim 27, wherein said level of expression of BAG-1 protein is determined by measuring the level of BAG-1 protein in a sample of breast tumor tissue.

53. (Previously amended) The method of claim 34, wherein said level of BAG-1 protein expression is determined by measuring the level of BAG-1 protein in a sample of breast tumor tissue.

54. (Previously amended) The method of claim 16, wherein said disease-free survival is distant metastasis-free survival.

55. (Previously amended) The method of claim 54, wherein said level of BAG-1 protein expression is determined by measuring the level of BAG-1 protein in a sample of breast tumor tissue.

56. (Previously amended) The method of claim 16, wherein said level of BAG-1 protein expression is determined by immunohistochemistry.

Inventor(s): John C. Reed
Serial No.: 09/350,518
Filed: July 9, 1999
Page 7

57. (Previously amended) The method of claim 55, wherein said level of BAG-1 protein expression is determined by immunohistochemistry.

58. (Previously amended) The method of claim 25, wherein said level of expression of BAG-1 protein is determined by immunohistochemistry.

59. (Previously amended) The method of claim 27, wherein said level of BAG-1 protein expression is determined by immunohistochemistry.

60. (Previously amended) The method of claim 34, wherein said level of BAG-1 protein expression is determined by immunohistochemistry.

61. (Previously amended) The method of claim 44, wherein said level of expression of BAG-1 protein is determined by immunohistochemistry.

62. (Previously added) The method of claim 16, wherein said level of BAG-1 protein expression is determined by measuring the level of BAG-1 protein in a sample of body fluid containing breast cancer cells.

63. (Previously added) The method of claim 25, wherein said level of BAG-1 protein expression is determined by measuring the level of BAG-1 protein in a sample of body fluid containing breast cancer cells.

64. (Previously added) The method of claim 27, wherein said level of expression of BAG-1 protein is determined by measuring the level of BAG-1 protein in a sample of body fluid containing breast cancer cells.

65. (Previously added) The method of claim 34, wherein said level of BAG-1 protein expression is determined by measuring the level of BAG-1 protein in a sample of body fluid containing breast cancer cells.

Inventor(s): John C. Reed
Serial No.: 09/350,518
Filed: July 9, 1999
Page 8

66. (Previously added) The method of claim 54, wherein said level of BAG-1 protein expression is determined by measuring the level of BAG-1 protein in a sample of body fluid containing breast cancer cells.